

REMARKS

In the Advisory Action dated August 16, 2006, the United States Patent and Trademark Office (hereinafter "the Office") maintained its rejections of all the claims in the pending patent application. Specifically, the Office raised four issues. First, the Office answered that the limitation "without the use of sales representative" does not mean that a prescriber order drug samples online. Second, the Office answered that the claim limitation "brand rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber" cannot be found in applicants' affidavit. Third, the Office answered that applicants' claims do not exclude the limitation of a server in a medical office to monitor the activities of prescribers. And, fourth, the Office answered that paragraph 283 of Feeney et al., which recites "central server maintains a database of all market drug products for appropriate retailers or service providers. From their own list of products, each retailer and service provider chooses the products or services to be promoted" does teach the limitation of one prescriber's drug sample availability to be different from another prescriber.

The Office was silent regarding whether the evidence submitted on July 14, 2006, responsive to the final Office Action was sufficient to show diligence in reduction to practice, signifying by the Office that the diligent issue has been resolved. Applicants appreciate the Office pointing out the lack of exclusion of a server in a medical office to distinguish the claimed invention from Feeney et al. Without admitting to the propriety of the rejections, applicants have amended Claim 1 to exclude the use of a server in a medical office of a prescriber so as to clarify the claimed invention. The claimed invention was also clarified by amendments made to Claims 16, 21, and 31.

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Prior to discussing in detail why applicants believe that all of the claims in this application are allowable, a brief description of applicants' invention and brief descriptions of the teachings of the cited and applied references are provided. The following discussions of the disclosed embodiments of applicants' invention and the teachings of the cited and applied references are not provided to define the scope or interpretation of any of the claims of this application. Instead, such discussions are provided to help the Office better appreciate important claim distinctions discussed thereafter.

The Affidavit Under 37 C.F.R. § 1.131

The Examiner, in the Advisory Action, indicated that the affidavit filed on December 7, 2005, under 37 C.F.R. § 1.131 is ineffective to overcome the Pham et al. reference because of two issues. First, the Office answered that the claim limitation "without the use of sales representative" does not mean that a prescriber can order drug samples online. Second, the Office answered that the claim limitation "brand rule" is not an obvious limitation that can be obtained from the affidavit, and therefore, even if the applicants could show to the Office support for the claim limitation "without the use of sales representative," the applicants do not have support for the whole invention.

Turning to the first issue, as described by the pending patent application, a prescriber can obtain drug samples either through the use of sales representatives or through ordering drug samples online via an entity that is authorized. Many prescribers would not risk their medical license by obtaining drug samples illegally. The Office's answer that the claim limitation "without the use of sales representative" does not mean that a prescriber order drug samples online is illogical. If the prescriber does not use a sales representative to obtain drug samples, his remaining legal option, in accordance with various embodiments of the present invention, is

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to obtain it via the use of the drug sample fulfillment platform discussed in the pending patent application. Also, the case law does not support the position taken by the Office. M.P.E.P. § 2131.01 provides that "[d]uring patent examination, the claims are given the broadest and reasonable interpretation consistent with the specification" (emphasis provided), citing favorably, *In re Morris*, 127 F.3d 1048, 44 U.S.P.Q. 2d 1023 (Fed. Cir. 1997). The applicants describe in the pending patent application at page 8, lines 5-7, that "[u]sing this method, prescribers 210 no longer need to rely on sales representatives to deliver physical samples." The method mentioned in the above quotation includes the use of the drug sample fulfillment platform which operates online.

The Office also was stuck at paragraph 1.2.4, page 4, of Exhibit A that "sales representatives . . . authorize release of additional vouchers." The Office interpreted this portion of the Exhibit A as "sales representative are [sic] needed to authorize the release of samples even if prescriber order them online." Page 4 of Exhibit 4 says nothing about the fact that a sales representative is needed to authorize release of additional vouchers. The verb "need" was inserted by the Office. Second, page 4 of the exhibit describes "release of additional vouchers." The word "additional" indicates that a prescriber must have obtained a voucher online without the use of sales representative prior to the need of obtaining "additional" vouchers. Yet, notwithstanding this very explicit disclosure of the exhibit, the Office eviscerated the word "additional" from the disclosure by stating that "sales representative are needed to authorize the release of samples." Such interpretation by the Office is not warranted, and in fact, the case law requires the Office to take the affidavit at face value. The applicants need do no more than make a *prima facie* showing of prior inventions. See *Ex parte McGuckin*, 202 U.S.P.Q. 398 (P.O.B.A. 1975); and *In re Eickmeyer*, 602 F.2d 974, 202 U.S.P.Q. 655, 660 (C.C.P.A. 1979).

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Regarding the second issue, the case law provides the following guidance with respect to showing for a 37 C.F.R. § 1.131 declaration:

We are convinced that under the law all the applicant can be required to show is priority with respect to so much of the claimed invention as the references [sic] happens to show. When he has done that he has disposed of the references

See *In re Stempel*, 241 F.2d 755, 113 U.S.P.Q. 77 (C.C.P.A. 1957). As discussed before, the Examiner on page 23 of the final Office Action indicates that brand rules can be based on "the specialty of the prescriber," citing applicants' specification at page 17, lines 20-22. Additionally, the Office indicated in the same final Office Action that Feeney et al. teaches at paragraph [0283] the use of physician practice for targeting promotions. If that is all that the Office can show in the applied references, applicants had already pointed out on page 20 of Exhibit B of the previously filed affidavit that the specialty of a physician is specified. Nevertheless, the Office asserted that applicants' affidavit mentions only the specialty of a physician and nothing else. That is not the case. Applicants refer the Office to page 2 of Exhibit B where it is described the ordering process of drug samples. The Office needs to appreciate that Exhibit B discusses the flow of pieces of software that alone or in combination comprise a portion of the cited drug sample fulfillment platform. Again, the Office is not taking the affidavit at face value and merely poking at the imperfections of expressions in an engineering document.

Summary of the Claimed Invention

Applicants' claimed invention is directed to a system for promoting pharmaceutical drugs, a drug sample fulfillment platform, a network system for ordering pharmaceutical sample drugs, and a method for accessing a drug sample fulfillment platform. The system form of the invention for promoting pharmaceutical drugs comprises a computer-readable set of brand rules

for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber. The system further comprises a computer-implementable drug sample fulfillment platform that is Web-based for implementing the set of brand rules to allow a prescriber to obtain drug samples to dispense to a patient without the use of a sales representative and without using a server in a medical office of the prescriber to monitor the activities of the prescriber.

Another system form of the invention includes a system for distributing pharmaceutical drugs that comprises a drug sample fulfillment platform for accessing drug sample services. The system further comprises a first set of Web pages coupled to the drug sample fulfillment platform through which a prescriber can access the drug sample fulfillment platform to order drug samples if a set of brand rules which specify drug sample availability and characteristics for the prescriber permits the prescriber to access the drug sample fulfillment platform.

Another system form of the invention includes a drug sample fulfillment platform which comprises a drug sample Web site for mating with a portal that is selected from a group consisting of prescriber-oriented Web portals, and e-detailing service, a Web site regarding a drug brand, and an online physician learning site. The system further comprises a request database for receiving requests of a prescriber through the drug sample Web site for drug samples. The request database responds to the prescriber by allowing the prescriber to print coupons or to print an order form for physical samples or pads of pre-printed vouchers if a set of brand rules allow the prescriber to receive drug samples in the form of print coupons, order forms for physical samples, or pads of pre-printed vouchers. The drug sample fulfillment platform notifies the prescriber when the prescriber has not ordered drug samples for a certain amount of time.

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Another system form of the invention includes a networked system for ordering pharmaceutical sample drugs. The system comprises a drug sample fulfillment platform that comprises a drug sample Web site for mating with a Web portal when a prescriber selects a hyperlink. The drug sample Web site presents a Web page including selectable options for the prescriber to order drug samples. The timeframe in which those drug samples are valid for the prescriber is specified by a set of brand rules. The Web page of the drug sample Web site conforms to the look and feel of the Web portal identified by a partner identifier and conforming to the look and feel of another Web portal identified by another partner identifier.

A method form of the invention includes a method for accessing a drug sample fulfillment platform which comprises activating a link to access the drug sample fulfillment platform from a Web portal. The method further comprises creating a transaction that includes a prescriber identifier and a partner identifier. The method yet further comprises mating a drug sample Web site to the Web portal allowing a prescriber to navigate and order drug samples only for drugs specified by a set of brand rules which include physical samples, pre-printed vouchers, and print coupons. The method also comprises shutting down redemptions through a pharmacy network by the drug sample fulfillment platform and disabling orders for drug samples in a sample program that has expired.

The Claims Distinguished

None of the cited and applied references teach "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber," as recited in Claim 1, among many other claim limitations. Another claim limitation that cannot be found in the cited and applied references is "a computer-implementable drug sample fulfillment platform

that is Web-based for implementing the set of brand rules to allow a prescriber to obtain drug samples to dispense to a patient without the use of a sales representative and without using a server in a medical office of the prescriber to monitor the activities of the prescriber," as recited in Claim 1, among many other claim limitations. Applicants continue being unable to find where the applied and cited references teach "a first set of Web pages coupled to the drug sample fulfillment platform through which a prescriber can access the drug sample fulfillment platform to order drug samples if a set of brand rules which specified drug sample availability and characteristics for the prescriber permits the prescriber to access the drug sample fulfillment platform," as recited in Claim 6, among other limitations. None of the cited and applied references teach limiting the access of a prescriber to the drug sample fulfillment platform based on brand rules. Feeney et al. teaches the reaching out by its system to the prescriber, and, therefore, there is no need to limiting access by the prescriber.

As a third example, none of the cited and applied references teach "the drug sample fulfillment platform notifying the prescriber when the prescriber has not ordered drug samples for a certain amount of time," as recited in Claim 16, among many other limitations. As a fourth example, none of the cited and applied references teach "the Web page of the drug sample Web site conforming to the look and feel of the Web portal identified by a partner identifier and conforming to the look and feel of another Web portal identified by another partner identifier," as recited in Claim 21, among many other limitations. As a fifth example, none of the cited and applied references teach "shutting down redemptions through a pharmacy network by the drug sample fulfillment platform and disabling orders for drug samples in a sample program that has expired," as recited in Claim 31, among other limitations.

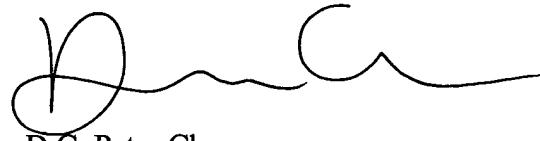
Because the Office has failed to state a *prima facie* case of obviousness, the rejections should be withdrawn. Amended independent Claims 1, 16, 21, and 31 and non-amended

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Claim 6 are clearly patentably distinguishable over the cited and applied references. Claims 2-5, 7-10, 17-20, 22-25, 32-45, and 51-55 are allowable because they depend from allowable independent claims and because of the additional limitations added by those claims. Consequently, reconsideration and allowance of Claims 1-10, 16-25, 31-45, and 51-55 is respectfully requested.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service in a sealed envelope as first-class mail with postage thereon fully prepaid and addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the below date.

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